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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/678,357	10/04/2000	Sven Mardh	SMAR.P001	4507

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EXAMINER	
SHAHNAN SHAH, KHATOL S	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 04/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/678,357	MARDH ET AL.	
	Examiner	Art Unit	
	Khatol S. Shahnan-Shah	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14,15,18-30 and 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-15,18-30 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 May 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' appeal brief and request for extension of time, received January 31, 2006 are acknowledged.

2. In view of the appeal brief filed on January 31, 2006, PROSECUTION IS HEREBY REOPENED. New rejections are set forth below. To avoid abandonment of the application, appellant must exercise one of the following two options: (1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or, (2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid. A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

Status of Claims

3. Claims 1-13, 16, 17, 31 and 33-34 have been canceled.

4. Claims 14-15, 18-30 and 32 are pending and under consideration.

Rejections Withdrawn

5. Rejection of the claims 14-15, 18-30 and 32 under USC § 103 (a) as being unpatentable over Oksanen et al. in view of Ma et al. is withdrawn.

New Objection

6. Claims 14, 18 and 19 are objected to because of the following informalities: Claim 14 contains a period after the multiplying step in the body of the claim. A claim should only end with a period.

Claim 18 broadens the scope of claim 14, from which it depends. Claim 18 recites wherein a lowered level of pepsinogen I concentration is indicative of corpus atrophy.

Claim 19 recites the negative limitation " without any autoimmunity involved ". There is insufficient antecedent basis for this limitation in the specification.

Appropriate correction is required.

New Rejections

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 18 and 19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 18 limitation "lowered level of pepsinogen I concentration is indicative of corpus atrophy" and claim 19 recites the negative limitation without any autoimmunity involved". However, there appears to be no descriptive support in the instant specification for these added limitations. Therefore the new limitation in the claims are considered new matter. *In re Rasussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step or a compound from a disclosure. See MPEP 608.04 and MPEP 2163.06.

Applicants are respectfully requested to point out the proper descriptive support in specific part (s) of the disclosure as filed, for the newly added limitations, or to remove the new matter from the claims.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 14-15, 18-30 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
Claim 14 recites the phrase "diagnosing possible presence of gastritis in a human". It is not clear what applicants intend in recitation of the above phrase. This is contradictory to the last step indicating the values are indicative of gastritis.
Claim 14 recites the phrase "wherein levels of H, K ATPase antibodies, Helicobacter antibodies, pepsinogen I concentration in the sample and the number obtained by the multiplying the level of pepsinogen I by the level of Helicobacter pylori antibodies that are different from the respective value in the normal population are indicative of gastritis". It is not clear what applicants intend in recitation of the above phrase.
Claim 14 recites the limitation "the respective values". There is insufficient antecedent basis for this limitation in the claim.
Claim 14 recites the limitation "the level of pepsinogen I". There is insufficient antecedent basis for this limitation in the claim.
Claim 14 recites the limitation "the level of Helicobacter pylori antibodies". There is insufficient antecedent basis for this limitation in the claim.
Claim 14 recites the limitation "the normal population". There is insufficient antecedent basis for this limitation in the claim.
Claim 14 recites the limitation "the concentration of pepsinogen I". There is insufficient antecedent basis for this limitation in the claim.

Claim 14 recites the "and" in the 4th line from the bottom lined through. Is the "and" deleted?

Claim 15, which depends from claim 15, recites the limitation "the steps of determining the levels". There is insufficient antecedent basis for this limitation in the claim 15 or 14.

Claim 21 recites, " Wherein a level of *Helicobacter pylori* antibodies differing from normal population is indicative of antrum of pan gastritis". It is not clear what applicants intend in said recitation. Antrum is not a condition or a disease it is a cavity or chamber in an organ. The antrum of stomach or gastric antrum is a portion before the outlet, which is lined by mucosa (see attached definitions from Medicine Net.com and Wikipedia).

Claims 18-19, 20, 22-30 and 32 are indefinite as being dependent from indefinite claims 14 and 15.

Art Rejection

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 14-15, 18-30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindgren et al. (European Journal of Gastroenterology and Hepatology, vol. 10, No. 7, pp. 583-588, 1998) prior art of record in view of Lin et al. (Journal of Gastroenterology vol. 30, pp. 156-161, 1995).

Claims are drawn to a method for diagnosing gastritis, evaluting blood samples for the presence of antibodies for H,K-ATPase , *Helicobacter pylori* and the concentration of pepsinogen I by immunoassay.

Lindgren et al. teach a method for diagnosing gastritis, evaluting blood samples for the presence of antibodies for H,K-ATPase , *Helicobacter pylori* and the concentration of pepsinogen A (pepsinogen I) by immunoassay (see abstract). Lindgren et al. teach that the antibodies to H,K-ATPase were determined using an enzyme-linked immunoaborbent assay, *Helicobacter pylori* antibodies were determined using enzyme immnuoassay and pepsinogen I serum level was determined by a double –antibody radioimmunoassay. Lindgren et al. teach not only the diagnostic performance of each test but also compare the various indicators or markers in combination to classify conditions (see morphological and serological findings and table 1 in page 585).

Lindgren et al. teach a method to compare the diagnostic performance of serum a*ntibodies to H,K-ATPase,* serum Pepsinogen A (same as Pepsinogen I) and the Schilling test in diagnosing chronic atrophic body gastritis; to study the interrelationships between H,K-ATPase antibodies, serology for *Helicobacter pylori*, and gastric morphology. Lindgren et al. teach relationship of the values of the indicators or markers in relation to different gastric pathologies (See table 1. , page 585). As to limitations of claims 19, 20, 26 and 27 about the autoimmune aspect of gastritis Lindgren et al. recite the relation of H,K-ATPase and autoimmune gastric atrophy (see pages 583 and 587). Lindgren et al. do not specifically teach the step of multiplying the level of pepsinogen by the level of *Helicobacter pylori* antibodies. Lin et al. teach using a scoring system in diagnosis of gasrtic endocarcinoma using combined assay of serological markers of *Helicobacter pylori,* pepsinogen I and gastrin (see title). Lin et al. teach multiplying value of pepsinogen I by the level of gastrin and devlop a scoring systm for diagnosis (see abstract). At the time the invention was made, it would have been *prima facie* obvious to a person of ordinary skill in the art to use scoring system of Lin et al. combined with the markers

measured of Lindgren et al. and provide a scoring system as taught by Lin et al. to multiply the level of pepsinogen I by the Helicobacter *pylori* antibodies to obtain the instant invention. It is *prima facie* obvious in the art and commonly known to one skilled in the art using a known scoring system in a different method of diagnosis since the analysis of multiple analytes or more indicators associated with gastritis provides reliable method for diagnosing gastritis.

One of ordinary skill in art would have been motivated to do this in order to obtain a method to simplify and optimize diagnostic techniques to detect multiple antibodies as markers in diagnosing disease such as gastritis related disease which are very common in human all around the world.

13. Claims 14-15, 18-30 and 32 are rejected under U.S.C. 103 (a) as being unpatentable over Oksanen et al. (Scandinavian Journal of Gastroenterology, Vol. 35, No. 8 pp 791-795, August 2000), in view of Ma J.Y. et al. (Scandinavian Journal of Gastroenterology, Vol. 29, No.11, pp961-965, 1994) and further

In view of Lin et al. (Journal of Gastroenterology vol. 30, pp. 156-161, 1995).

Claims are drawn to a method for diagnising gastritis, evaluting blood samples for the presence of antibodies for H,K-ATPase , *Helicobacter pylori* and the concentration of pepsinogen I by immunoassay.

Oksanen et al. evaluated serum samples to predict normal gastric mucosa by studying the serum samples for *Helicobacter pylori* antibodies by enzyme immunoassay (Pyloriset EIA-G and EIA-A) and pepsinogen I was measured by an immunoenzymometric assay (Gastrotest PGI). Oksanen et al. teach not only the diagnostic performance of each test but also compare the various indicators or markers in combination to classify different gastric conditions or pathologies (see pages 792-793 and tables 1, 2, 3). Oksanen et al. did not teach assaying for H, K-ATPase antibodies.

Ma J.Y. et al. studied sera from patients with pernicious anemia by means of enzyme-linked immunosorbent assay for the occurrence of antibodies against H, K-

ATPase and *Helicobacter pylori.* As to limitations of claims 19, 20, 26 and 27 about the autoimmune aspect of gastritis Ma J.Y. et al. recite the relation of H,K-ATPase and autoimmune atrophic corpus gastritis (see abstract). It is *prima facie* obvious that the combination of two methods each of which is taught in the prior art to be useful for the same purpose, in order to form a third combination of those methods which would be used for the very same purpose. In this case the method of Oksanen et al. and Ma J.Y. et al., teach assaying blood for the presence of antibodies specific for H, K-ATPase ,*Helicobacter pylori* and pepsinogen I; comparing the results of the sample to results of normal populations, performing mathematical analysis on the test results and determining the different values are indicative of gastritis, atrophic corpus gastritis, chronic gastritis and gastritis without any autoimmunity, just as instantly claimed. Oksanen et al. and Ma J.Y. et al. do not specifically teach the step of multiplying the level of pepsinogen I by the level of *Helicobacter pylori* antibodies. Lin et al. teach using a scoring system in diagnosis of gasrtic endocarcinoma using combined assay of serological markers of *Helicobacter pylori,* pepsinogen I and gastrin (see title). Lin et al. teach multiplying value of pepsinogen I by the level of gastrin and develop a scoring system for diagnosis(see abstract). At the time the invention was made, it would have been *prima facie* obvious to a person of ordinary skill in the art to use scoring system of Lin et al. combined with the markers of Oksanen et al. and Ma J.Y. et al. and provide a scoring system as taught by Lin et al. to multiply the level of pepsinogen I by the Helicobacter *pylori* antibodies to obtain the instant invention. It is *prima facie* obvious in the art and commonly known to one skilled in the art using a known scoring system in a different method of diagnosis since the analysis of multiple analytes or more indicators associated with gastritis provides reliable method for diagnosing gastritis.

One of ordinary skill in art would have been motivated to do this in order to obtain a method to simplify and optimize diagnostic techniques to detect multiple antibodies

as markers in diagnosing disease such as gastritis related disease which are very common in human all around the world.

Conclusion

14. No claims are allowed.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is 571-272-0863. The examiner can normally be reached on Monday-Friday 7:30 AM-5:00 PM If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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